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No. 01-441

IN THE

Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

Respondent Medtronic, Inc. does not contest that the petition presents an important federal preemption question under the Medical Device Amendments ("MDA") that has divided the federal and state appellate courts. The split in authority is illustrated most pointedly by decisions of the federal courts of appeal, including the decision below, that have arrived at diametrically opposed legal conclusions on the question presented in cases involving the same defendant and the same medical device. *See* Pet. 3-4. In opposition, respondent asserts, first, that review should be denied because review was denied in *Kemp v. Medtronic, Inc.*, No. 00-1766, a case that it asserts is "virtually identical" to the present case. Opp. 1, 14; *see* Opp. 27. Respondent also claims that the split in authority, although genuine, does not warrant this Court's attention. Medtronic's arguments are incorrect, and the Court should grant the petition.

I. THE DENIAL OF CERTIORARI IN *KEMP* IS IRRELEVANT.

Respondent now claims that *Kemp* presented the same question as that presented here, both beginning and ending its opposition on that theme. Opp. 1, 27. However, that is not what respondent said in its *Kemp* opposition. Indeed, respondent began that opposition by restating the question presented and then asserting, "[h]owever, as we explain in this brief, that question is not in fact presented by this case." Brief for the Respondent in Opposition in *Kemp v. Medtronic, Inc.*, No. 00-1766, at (I) (filed July 23, 2001). Respondent then argued, as the *principal* basis for denying review, that the Kemps were requesting "nothing but an improper advisory opinion" because they had "raised only three claims in the Sixth Circuit...[,] *none of which is before this Court.*" *Id.* at 15 (emphasis in original); *see also id.* at 15-16 (same).

By contrast, here, although respondent claims that "like *Kemp*," this case "is not the vehicle to clarify" the question presented, Opp. 1, respondent does not — because it cannot — claim that the MDA preemption question posed by petitioners is not squarely presented. Thus, quite apart from the ordinary rule that a denial of certiorari carries no weight, if this Court denied review in *Kemp* on the main basis urged by respondent, the Court's disposition in *Kemp* is irrelevant.

Unable to argue directly that the preemption issue is not presented, respondent seeks to obscure the legal issue with a particularly extended discussion of facts and procedural history that quibbles with the petition on some incidental details. Only one of respondent's assertions requires correction at this juncture because of its potential for confusion: respondent's statement that the district court did not hold all of petitioners' claims preempted. Opp. 11. An examination of the district court's orders shows clearly that it did. Pet. App. 23a-48a. That the district court recognized that some claims *not* advanced by petitioners would not be preempted is beside the point. *See* Pet. 11-12.

II. THE QUESTION PRESENTED INVOLVES A DEEP AND UNRESOLVED SPLIT IN AUTHORITY THAT CALLS FOR RESOLUTION BY THE COURT AT THIS TIME.

Respondent contends that the Court should deny review because the decision in *Buckman Company v. Plaintiffs' Legal Committee*, 121 S. Ct. 1012 (2001), may alter the legal terrain and because the split in authority among the lower courts is not as serious as petitioners maintain. Neither contention is persuasive.

A. Respondent asserts that the Court should defer review because *Buckman* "may assist [lower] courts" in resolving the question presented. Opp. 15. Respondent ignores

the key reason why *Buckman* is irrelevant here: In holding that a fraud-on-the-FDA claim is impliedly preempted by federal law, *Buckman* explicitly distinguished claims, such as those at issue here, that "rely[ ] on traditional state tort law which had predated the federal [MDA] enactments in question." 121 S. Ct. at 1020.

Beyond that basic omission, respondent makes three points related to *Buckman*, none of which has merit. First, it notes that *Buckman* said that the PMA process is "thorough" compared to the 510(k) process at issue in *Lohr*. Opp. 15. Actually, *Buckman* mentioned that point only in passing, 121 S. Ct. at 1015, as the device at issue there was not a PMA device. *Id.* at 1015-16.

Second, respondent asserts that *Buckman* clarified that, under *Lohr*, only "certain" state-law causes of action that parallel federal requirements may go forward. Opp. 15. That supposed clarification also has nothing to do with this case. Petitioners certainly maintain that their claims are compatible with, *i.e.*, not "different from, or in addition to[,]" federal law — for instance, their manufacturing-defect claim is fully consistent with the FDA's good manufacturing practices rules, *see* 20 C.F.R. Part 820. However, their causes of action are based exclusively on general state-law claims regarding manufacturing and design defect and failure to warn, Pet. 11, not on claims of negligence *per se* for violations of federal rules. Equally important, the principal cases reflecting the deep divide among the lower courts also involve general state-law claims. *See, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369 (11th Cir. 1999); *Oja v. Howmedica*, 111 F.3d 782, 784-85 (10th Cir. 1997); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1151 (Ill. 1999); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 906 (7th Cir. 1997). Thus, none of those precedents could possibly be affected by *Buckman*'s comment regarding state-law causes of action that parallel federal requirements.

Third, respondent relies on *Buckman*'s statement that a state-law fraud-on-the-FDA claim would disrupt the balance that Congress was trying to achieve under the MDA. Opp. 15-16. That implied preemption rationale does not relate to the question presented here — whether 21 U.S.C. 360k(a) expressly preempts the Kemps' claims based on "traditional state tort law." *Buckman*, 121 S. Ct. at 1020. In this regard, it is important to consider what was at issue in *Buckman*. The theory of the case was unrelated to whether the product was properly designed or manufactured or accompanied by appropriate warnings; rather, it was premised entirely on the notion that the product would not have been marketed if not for the defendant consultant's fraudulent submissions to the FDA. Thus, the Court's concern about the balance struck by Congress related to the potential for interference with the internal workings of the FDA, *id.*, not with the independent tortious conduct of device manufacturers in their interactions with device users and physicians, which is the basis for petitioners' claims. Moreover, the Court's ruling was based solely on *implied preemption* principles and did not even discuss whether a fraud-on-the-FDA claim, let alone the "traditional state tort law" claims at issue here, is preempted by the MDA's express preemption provision, 21 U.S.C. 360k(a). Indeed, *Buckman*'s only reference to section 360k(a) is in a footnote stating that the Court would *not* consider the question whether a fraud-on-the-FDA claim is expressly preempted. 121 S. Ct. at 1017 n.2. In sum, the fraud-on-the-FDA ruling in *Buckman* has no bearing on the question presented here.

Respondent's argument is necessarily based on the premise that post-*Buckman* express preemption cases involving PMA devices will be influenced by *Buckman*. That premise is wrong. *Buckman* has played no role in PMA cases finding preemption, such as *Kemp* and the decision below, or in cases finding no preemption. Indeed, the most recent federal court

decision to address this issue followed the Eleventh Circuit's no-preemption holding in *Goodlin*, and, although it cited *Buckman* in passing, it did not find that decision relevant to, let alone dispositive of, the express preemption issue. *See Webster v. Pacesetter, Inc.* ___ F. Supp. 2d ___, 2001 WL 1359969 (D.D.C. Nov. 1, 2001).

The very few cases that have addressed whether *Buckman* alters the preemption analysis are, not surprisingly, *implied preemption* cases involving drugs (not devices), and every one of them has rejected preemption on the ground that *Buckman*'s fraud-on-the-FDA analysis does not apply to "traditional" tort claims against the product manufacturer. *See Caraker v. Sandoz Pharmaceuticals Corp.*, ___ F. Supp. 2d ___, 2001 WL 1190858, *16-*17 (S.D. Ill. Sept. 4, 2001); *Dawson v. Ciba-Geigy Corp.*, 145 F. Supp. 2d 565, 572-73 (D.N.J. 2001); *Globetti v. Sandoz Pharmaceuticals Corp.*, 2001 WL 419160, *1-*2 (N.D. Ala. Mar. 5, 2001). In sum, neither logic nor even a sliver of case authority supports respondent's argument that *Buckman* provides a basis to deny review.*

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*In this regard, respondent's reliance on *Brooks v. Howmedica, Inc.*, 226 F.3d 966 (8th Cir.), *reh'g en banc granted*, 246 F.3d 1149 (8th Cir. 2001), *see* Opp. 16, is misplaced. *Brooks* involves solely the question whether a traditional state-law failure-to-warn claim is expressly preempted by section 360k(a), and does not present design or manufacturing-defect claims like those presented here. Respondent appears to find significance in the fact that rehearing en banc was granted in *Brooks* the day after *Buckman* was decided. *See* Opp. 16. However, the timing of the *Brooks* order is obviously happenstance, unless one believes that, sensing a need to act immediately, the full complement of Eighth Circuit judges read this Court's decision, conferred, and granted the en banc petition within 24 hours.

B. Respondent's argument that the current split of authority among the federal courts of appeals and state courts of last resort is not significant, Opp. 16-21, is largely answered by the petition and we do not repeat it here. *See* Pet. 14-18. Moreover, although the continuing division among intermediate state appellate courts — the existence of which respondent does not contest — may not be an independent basis for granting certiorari under this Court's Rule 10, it does show that the division among the courts of appeals and the state courts of last resort is creating broad confusion in the judicial system that requires this Court's attention. In any event, respondent's claim of a shallow split is rhetorical, as the opposition's main thrust is not that the split is insignificant, but rather a critique of the merits of the key decisions with which respondent disagrees. Opp. 18-21. That the courts have taken differing views on the merits, however, only underscores the need for review.

Two of respondent's specific assertions warrant correction. First, respondent claims that the Kentucky Supreme Court's decision in *Niehoff v. Surgidev Corp.*, 950 S.W. 2d 816 (Ky. 1997), is inapposite because the device there went through the investigational device process, not the PMA process. Opp. 19 n.7. However, *Niehoff* held both that the investigational device process does not trigger preemption *and* that state-law tort claims based on duties of general applicability are not sufficiently specific to trigger preemption under 21 U.S.C. 360k(a). That latter holding applies with equal force to claims involving PMA devices and directly conflicts with the decision below. Respondent's assertion that *Niehoff* did not so hold, Opp. 21 n.10, is belied not only by the language of the decision itself, *see* 950 S.W. 2d at 822 ("Kentucky's strict liability case law and statutes [on which the plaintiff relied] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"), but also by the Kentucky Court of Appeals' decision in *Leslie v. Cincinnati*

Sub-zero Products, Inc., 961 S.W. 2d 799, 802-03 (Ky. App. 1998), whose understanding of *Niehoff* is identical to that of petitioners.

Second, we reiterate that, in December 1997, *before* the Eleventh Circuit's decision in *Goodlin* and the Illinois Supreme Court's decision in *Weiland*, the Solicitor General maintained that the "current division" in the courts would have called for review by this Court, except for unusual circumstances not present here. *See* Pet. 20-21 & n.5 (discussing Solicitor General's amicus brief in *Smith Industries Medical Systems v. Kernats*, No. 96-1405). Respondent's assertion that the government's position in *Kernats* was based on the pendency of a now-withdrawn proposed FDA regulation is flatly incorrect. The Solicitor General argued at length that the no-preemption decision in *Kernats* was correct. *See* Brief for the United States as Amicus Curiae in *Smith Indus. Med. Sys., Inc. v. Kernats*, No. 96-1405, at 14-18 (U.S. filed Dec. 10, 1997). That merits argument was unrelated to the proposed regulation, which was discussed at the very end of the brief only as a reason to deny review. *Id.* at 19-20. Moreover, contrary to respondent's insinuation, *see* Opp. 27 n.13, the United States specifically noted that the position it took in *Buckman* was consistent with the position it had taken in *Kernats*. *See* Brief for the United States as Amicus Curiae in *Buckman Co. v. Plaintiffs' Legal Committee*, No. 98-1768, at 5 n.2 (U.S. filed June 7, 2000) (petition stage).

C. Even further afield is respondent's speculation that courts that have rejected preemption may revisit their no-preemption holdings, and that this Court should therefore deny review because the split in authority will go away. Absent a decision of this Court finding preemption on the question presented, there would be no lawful basis for such an about-face. Indeed, we know of no case in the Tenth Circuit (where *Oja* prevails), in the Eleventh Circuit (where *Goodlin* prevails),

in the Illinois state courts (where *Weiland* prevails), or in the Kentucky state courts (where *Niehoff* prevails) in which a defendant device manufacturer is arguing that *Buckman* or some other development requires that controlling precedent be set aside. Presumably respondent — the world's largest device manufacturer and a frequent litigant — would have brought such cases to this Court's attention if there were any. Indeed, even in state court systems where intermediate appellate courts have issued no-preemption decisions (New York, Michigan, Oregon, New Jersey, and California), *see* Pet. 16, 18, we know of no challenges to those decisions in the areas in which they control, and, again, respondent has not pointed to any.

* * *

To summarize: Petitioners' claims would not be preempted in the states comprising the Eleventh Circuit or in the state courts of Illinois, where controlling precedent holds that the PMA process does not result in specific federal requirements that are preemptive under the MDA. Nor would their claims be preempted in the Tenth Circuit or in Kentucky courts, where controlling precedent holds that state-law duties of the kind relied on by petitioners do not establish specific state-law requirements subject to preemption under the MDA.

III. RESPONDENT'S ARGUMENTS ON THE MERITS UNDERSCORE THE NEED FOR REVIEW.

The petition briefly explains why the ruling below on the merits is inconsistent with the text and purpose of the MDA and this Court's decision in *Lohr*. Pet. 20-22. Respondent, of course, argues that the ruling below is correct. Opp. 22-27. The parties' disagreements are very wide. For instance, whereas respondent argues that FDA pre-market approval transforms all specifications of the manufacturer's application

into preemptive federal requirements, Opp. 23, petitioners maintain that such specifications originate with the manufacturer, not FDA, and thus are not specific federal requirements that have preemptive force. Pet. 20. The petition and opposition reveal the parties' very different understanding of the law and of the significance of the facts concerning approval of the pacemaker leads that caused petitioners' injuries. If this Court grants review, there will be time enough to reply to respondent's merits arguments in detail. However, for present purposes, the depth of the disagreement on the merits only emphasizes the need for review. As is evident from the parties' submissions, some courts have sided with the petitioners on the merits and others with respondent. Their positions are irreconcilable and can only be resolved by this Court.

CONCLUSION

For the reasons stated above and in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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